

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of	) Attorney Docket No.: ASHTON0009
Wesley Scott ASHTON	)
Serial No.: 10/697,083	) Confirmation No.: 9725
Filed: October 31, 2003	)
	) Group Art Unit: 3677
	)
	) Examiner: David C. Reese
	)
For: TONGUE AND MOUTH STUD	) Date: January 19, 2011
FOR DISPENSING A SUBSTANCE	

**APPEAL BRIEF**

**MAIL STOP: APPEAL**  
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Sir:

Applicant respectfully submits this Appeal Brief, under 37 C.F.R. § 41.37 with respect to the above-captioned application, to the Board of Patent Appeals and Interferences ("Board"). The present Appeal Brief addresses and responds to all outstanding issues set forth in the Final Office Action mailed August 19, 2010.

**Real Party in Interest**

The inventor, Wesley Scott Ashton, is the real party in interest.

**Related Appeals and Interferences**

There are no related appeals or interferences with respect to the present appeal.

**Status of Claims**

Claims 21-27, 31, 36-39, and 42-49 stand rejected. Claims 1-20, 28-30, 32-35, 40 and 41 are cancelled.

Claims 21-27, 31, 36-39, and 42-49 are under appeal. A copy of the appealed claims is provided in Appendix A attached hereto.

**Status of Amendments**

Amendment (K) filed on July 12, 2010 has been entered per the Final Office Action, mailed August 19, 2010, at 2, lines 2-5. No claim amendments were filed subsequent to final rejection.

**Summary of Claimed Subject Matter**

The present invention pertains broadly to a method for dispensing a substance into a mouth, which employs a mouth and tongue stud including a means for dispensing a substance, such as could be used to dispense a breath freshener, a flavoring agent, a medication, or a combination of these substances to the wearer's tongue (See Applicant's original specification, at 2, line 16, to 3, line 9). The independent claims under appeal are claims 21, 31, 36-39, 44 and 45.

Claim 21 recites a method embodiment, in accordance with the invention, that pertains to a method for dispensing a substance into a mouth, wherein the substance is selected from the group consisting of a breath freshener and a flavoring agent, and the method comprises the steps of: providing a mouth and tongue stud including a means for dispensing a substance formed in a portion of the stud, wherein the means for dispensing a substance contains the substance and wherein the stud further comprises a bar having ends, a first end member attached to one end of the bar and a second end member attached to an other end of the bar, and the first end member removably attaches to the one end of the bar; mounting the bar of the stud in a fistula formed in a wearer's tongue; and dispensing the substance into the wearer's mouth, wherein the substance is dispensed on or below, or on and below, the wearer's tongue solely by dissolving the substance over time in the wearer's saliva so that the dissolved substance is free to flow from the means for dispensing to on or below, or on

and below, the wearer's tongue (See, e.g., Applicant's original specification, page 2, line 16, to page 3, line 9, and page 7, lines 10-15, and on page 9, lines 3-8; and Preliminary Amendment (A), filed October 31, 2003, page 4, lines 8-13).

Claim 22 depends upon claim 21 and further recites that the substance comprises a breath freshener (See, e.g., Applicant's original specification, page 5, lines 6-8; and Preliminary Amendment (A), filed October 31, 2003, page 4, lines 13-14). Claim 23 depends upon claim 21 and further recites that the substance comprises a flavoring agent (See, e.g., Applicant's original specification, page 5, lines 6-8; and Preliminary Amendment (A), filed October 31, 2003, page 4, lines 14-15). Claim 24 depends upon claim 23 and further recites that the substance includes a breath freshener mixed with the flavoring agent (See, e.g., Applicant's original specification, page 5, lines 6-8; and Preliminary Amendment (A), filed October 31, 2003, page 4, lines 15-17).

Claim 25 depends upon claim 22 and further recites that a medication is mixed with the breath freshener (See, e.g., Applicant's original specification, page 5, lines 6-8; and Preliminary Amendment (A), filed October 31, 2003, page 4, lines 17-18). Claim 26 depends upon claim 23, and further recites that a medication is mixed with the flavoring agent (See, e.g., Applicant's original specification, page 5, lines 6-8; and Preliminary Amendment (A), filed October 31, 2003, page 4, lines 18-20). Claim 27 depends upon claim 24, and further recites that a medication is mixed with the breath freshener and the flavoring agent (See, e.g., Applicant's original specification, page 5, lines 6-8; and Preliminary Amendment (A), filed October 31, 2003, page 4, line 20, to page 5, line 2).

Claim 46 depends upon claim 22, and further recites that the bar is a solid bar that is without an internal cavity, and the means for dispensing a substance is formed in the second end member (See, e.g., Applicant's original specification, page 5, line 23, to page 6, line 20, and page 9, lines 16-21).

The embodiment of independent claim 31 pertains to a method for dispensing a substance into a mouth, wherein the substance is a medication, and the method comprises the steps of: providing a mouth and tongue stud including a means for dispensing a substance formed in a portion

of the stud, wherein the means for dispensing a substance contains the medication and wherein the stud comprises a bar having ends, a first end member attached to one end of the bar and a second end member attached to an other end of the bar, and the first end member removably attaches to the one end of the bar; mounting the bar of the stud in a fistula formed in a wearer's tongue; and dispensing the medication into the wearer's mouth, wherein the substance is dispensed on or below, or on and below, the wearer's tongue solely by dissolving the substance over time in the wearer's saliva so that the dissolved substance is free to flow from the means for dispensing to on or below, or on and below, the wearer's tongue (See, e.g., Applicant's original specification, page 2, line 16, to page 3, line 9, and page 6, lines 10-13, and page 7, lines 10-15, and on page 9, lines 3-8; and Preliminary Amendment (A), filed October 31, 2003, page 4, lines 8-13, and by original claims 1, 26 and 27).

Claim 47 depends upon claim 31, and further recites that the bar is a solid bar that is without an internal cavity, and the means for dispensing a substance is formed in the second end member (See, e.g., Applicant's original specification, page 5, line 23, to page 6, line 20, and page 9, lines 16-21).

An embodiment, according to independent claim 36, pertains to a method for dispensing a substance into a mouth, wherein the substance is selected from the group consisting of a breath freshener and a flavoring agent, and the method comprises the steps of: providing a mouth and tongue stud including a means for dispensing a substance formed in a portion of the stud, wherein the means for dispensing a substance contains the substance and wherein the stud comprises a bar having ends, a first end member attached to one end of the bar and a second end member attached to an other end of the bar, wherein the bar is a straight solid bar that is without an internal cavity and that is made of metal and the first end member removably attaches to the one end of the bar, and wherein the means for dispensing a substance is formed in one or both of the first end member and the second end member; mounting the bar of the stud in a fistula formed in a part of a wearer's mouth; and dispensing the substance into the wearer's mouth, wherein the substance is dispensed on or below, or on and below, the wearer's tongue solely by dissolving the substance over time in the wearer's saliva

(See, e.g., Applicant's original specification, page 1, lines 6-10, and page 2, line 16, to page 3, line 9, and page 4, lines 15-22, and page 7, lines 10-15, and on page 9, lines 3-8; and Preliminary Amendment (A), filed October 31, 2003, page 4, lines 8-15, and original claim 7).

An embodiment, according to independent claim 37, pertains to a method for dispensing a substance into a mouth, wherein the substance is a medication, and the method comprises the steps of: providing a mouth and tongue stud including a means for dispensing a substance formed in a portion of the stud, wherein the means for dispensing a substance contains the medication and wherein the stud comprises a bar having ends, a first end member attached to one end of the bar and a second end member attached to an other end of the bar, wherein the bar is a straight solid bar that is without an internal cavity and that is made of metal and the first end member removably attaches to the one end of the bar, and wherein the means for dispensing a substance is formed in one or both of the first end member and the second end member; mounting the bar of the stud in a fistula formed in a part of a wearer's mouth; and dispensing the medication into the wearer's mouth, wherein the medication is dispensed on or below, or on and below, the wearer's tongue solely by dissolving the medication over time in the wearer's saliva (See, e.g., Applicant's original specification, page 1, lines 6-10, and page 2, line 16, to page 3, line 9, and page 4, lines 15-22, and page 7, lines 10-15, and on page 9, lines 3-8; and Preliminary Amendment (A), filed October 31, 2003, page 4, lines 8-15, and original claim 7).

An embodiment, according to independent claim 38, pertains to a method for dispensing a substance into a mouth, wherein the substance is selected from the group consisting of a breath freshener and a flavoring agent, and the method comprises the steps of: providing a mouth and tongue stud including a means for dispensing a substance formed in a portion of the stud, wherein the means for dispensing a substance contains the substance and wherein the stud further comprises a bar having ends, a first end member attached to one end of the bar and a second end member attached to an other end of the bar, and the first end member removably attaches to the one end of the bar, and wherein an insert is disposed in the means for dispensing a substance; mounting the bar of the stud in a fistula

formed in a wearer's tongue so that the first end member and the second end member hold the stud in the fistula; and dispensing the substance into the wearer's mouth, wherein the substance is dispensed into the wearer's mouth on or below, or on and below, the wearer's tongue by diffusing the substance from the stud into the wearer's mouth over time in the wearer's saliva (See, e.g., Applicant's original specification, page 2, line 3, to page 3, line 9, and page 4, lines 20-22, and page 5, lines 8-12, and page 7, lines 10-15, and on page 9, lines 3-8; and Preliminary Amendment (A), filed October 31, 2003, page 4, lines 8-13).

Claim 48 depends upon claim 38, and further recites that the substance comprises a liquid (See, e.g., Applicant's original specification, page 9, lines 14-16).

The embodiment, according to independent claim 39, pertains to a method for dispensing a substance into a mouth, wherein the substance is a medication, and the method comprises the steps of: providing a mouth and tongue stud including a means for dispensing a substance formed in a portion of the stud, wherein the means for dispensing a substance contains the substance and wherein the stud further comprises a bar having ends, a first end member attached to one end of the bar and a second end member attached to an other end of the bar, and the first end member removably attaches to the one end of the bar, and wherein an insert is disposed in the means for dispensing a substance; mounting the bar of the stud in a fistula formed in a wearer's tongue so that the first end member and the second end member hold the stud in the fistula; and dispensing the substance into the wearer's mouth, wherein the substance is dispensed into the wearer's mouth on or below, or on and below, the wearer's tongue by diffusing the substance from the stud into the wearer's mouth over time in the wearer's saliva (See, e.g., Applicant's original specification, page 2, line 3, to page 3, line 9, and page 4, lines 20-22, and page 5, lines 8-12, and page 7, lines 10-15, and on page 9, lines 3-8; and Preliminary Amendment (A), filed October 31, 2003, page 4, lines 8-13).

Claim 49 depends upon claim 39, and further recites that the substance comprises a liquid (See, e.g., Applicant's original specification, page 9, lines 14-16).

The embodiment, according to independent claim 44, pertains to a method for dispensing a

substance into a mouth, wherein the substance is selected from the group consisting of a breath freshener and a flavoring agent, and the method comprises the steps of: providing a mouth and tongue stud including a means for dispensing a substance formed in a portion of the stud, wherein the means for dispensing a substance contains the substance and wherein the stud further comprises a bar having ends, a first end member attached to one end of the bar and a second end member attached to an other end of the bar, and the first end member removably attaches to the one end of the bar; mounting the bar of the stud in a fistula formed in a wearer's tongue so that the first end member and the second end member hold the stud in the fistula; and dispensing the substance into the wearer's mouth, wherein the substance has a form selected from the group consisting of a solid form and a tablet form and is dispensed on or below, or on and below, the wearer's tongue by dissolving the substance from the stud to flow on or below, or on and below, the wearer's tongue over time in the wearer's saliva (See, e.g., Applicant's original specification, page 2, line 3, to page 3, line 9, and page 4, lines 20-22, and page 6, lines 10-13, and page 7, lines 10-15, and on page 9, lines 3-8; and Preliminary Amendment (A), filed October 31, 2003, page 4, lines 8-13).

Claim 42 depends upon claim 44 and further recites that the substance has a solid form and the solid form is a solid crystallized form (See, e.g., Applicant's original specification, page 6, lines 10-13).

The embodiment, according to independent claim 45, pertains to a method for dispensing a substance into a mouth, wherein the substance is a medication, and the method comprises the steps of: providing a mouth and tongue stud including a means for dispensing a substance formed in a portion of the stud, wherein the means for dispensing a substance contains the substance and wherein the stud further comprises a bar having ends, a first end member attached to one end of the bar and a second end member attached to an other end of the bar, and the first end member removably attaches to the one end of the bar; mounting the bar of the stud in a fistula formed in a wearer's tongue so that the first end member and the second end member hold the stud in the fistula; and dispensing the substance into the wearer's mouth, wherein the substance has a form selected from the group

consisting of a solid form and a tablet form and is dispensed on or below, or on and below, the wearer's tongue by dissolving the substance from the stud to flow on or below, or on and below, the wearer's tongue over time in the wearer's saliva (See, e.g., Applicant's original specification, page 2, line 3, to page 3, line 9, and page 4, lines 20-22, and page 6, lines 10-13, and page 7, lines 10-15, and on page 9, lines 3-8; and Preliminary Amendment (A), filed October 31, 2003, page 4, lines 8-13).

Claim 43 depends upon claim 45 and further recites that the substance has a solid form and the solid form is a solid crystallized form (See, e.g., Applicant's original specification, page 6, lines 10-13).

**Grounds of Rejection to be Reviewed on Appeal**

Claims 21-27, 36, 44 and 46 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Kaping, Jr. (U.S. Patent 6,026,659, hereafter the "Kaping Patent") in view of Kasdin et al. (U.S. Patent 3,503,127, hereafter the "Kasdin Patent"). Claims 38 and 48 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over the Kaping Patent in view of Sipos (U.S. Patent 3,600,807, hereafter the "Sipos Patent"). Claims 31, 37, 39, 42, 43, 45 and 47 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over the Kaping Patent in view of Cox (U.S. Patent 4,959,052, hereafter the "Cox Patent"). Claim 49 stands rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over the Kaping Patent in view of the Cox Patent, and further in view of the Kasdin Patent.



**TABLE OF CONTENTS**

Real Party in Interest.....	1
Related Appeals and Interferences.....	1
Status of Claims.....	2
Status of Amendments.....	2
Summary of Claimed Subject Matter.....	2
Grounds of Rejection to be Reviewed on Appeal.....	8
Applicant's Arguments.....	11
1.    A <u>Prima Facie</u> Case of Obviousness Under 35 U.S.C § 103 Has Not Been Established Because the Art of Record Does not Disclose Every Claimed Limitation, there is no Legitimate Reason to Modify the Art as Proposed, and There is No Reasonable Expectation of Success of Obtaining the Claimed Method Even if the Combination Asserted by the Examiner was Made.....	11
A.    Claims 21-27, 31, 36-39, and 42-49.....	12
i.    The Kaping Patent.....	12
ii.   The Kasdin Patent.....	13
a.  The Kasdin Patent is Non-analogous Art.....	15
iii.  The Cox Patent.....	18
a.  The Cox Patent is Non-analogous Art.....	21
iv.   The Sipos Patent.....	25
a.  The Sipos Patent is Non-analogous Art.....	27
v.    Summary of the Disclosures.....	30
vi.   The Examiner's Retrospective View of Inherency is Improper and Should be Withdrawn.....	32
vii.  The Examiner has Not Established a <u>Prima Facie</u> Case of Obviousness Because There is No Plausible Rationale to Justify Combining the Disclosures of the Kasdin Patent, the Cox Patent and the Sipos Patent with the Kaping Patent.....	34

viii.	The Examiner has not Established a <u>Prima Facie</u> Case of Obviousness Because the Examiner Failed to Demonstrate a Reasonable Expectation of Success Even if the Combinations Proposed by the Examiner Were Made.....	36
ix.	The Examiner's Arguments with Respect to Ordinary Creativity, Common Knowledge and Common Sense are Untenable and Must be Withdrawn.....	39
x.	Applicant's Novel Invention Possesses a New Property that Merits Patentability.....	41
B.	Claims 21-27, 36, 44 and 46.....	41
C.	Claims 38 and 48.....	43
D.	Claims 31, 37, 39, 42, 43, 45 and 47.....	43
E.	Claim 49.....	45
2.	CONCLUSION.....	46
	CLAIMS APPENDIX (A).....	47
	EVIDENCE APPENDIX (B).....	54
	RELATED PROCEEDINGS APPENDIX (C).....	55

**Applicant's Arguments**

**1. A Prima Facie Case of Obviousness Under 35 U.S.C § 103 Has Not Been Established Because the Art of Record Does not Disclose Every Claimed Limitation, There is no Legitimate Reason to Modify the Art as Proposed, and There is No Reasonable Expectation of Success of Obtaining the Claimed Method Even if the Combination Asserted by the Examiner was Made**

A prima facie case of obviousness requires a showing that the scope and content of the prior art teaches each and every element of the claimed invention, and that the prior art provides some teaching, suggestion or motivation, or other legitimate reason, to combine the references to produce the claimed invention. KSR International Co. v. Teleflex Inc., 127 St. Ct. 1727, 1742 (2007); In re Oetiker, 24 U.S.P.Q.2d 1443 (Fed. Cir. 1992). A proper rejection under Section 103 also requires showing (1) that the prior art would have suggested to a person of ordinary skill in the art that they should make the claimed device or carry out the claimed process, (2) that the prior art would have revealed to a person of ordinary skill in the art that in so making or doing, there would have been a reasonable expectation of success, and (3) both the suggestion and the reasonable expectation of success must be found in the prior art and not in the applicants' disclosure. PharmaStem Therapeutics, Inc. v. ViaCell, Inc., 491 F.3d 1342, 1360 (Fed. Cir. 2007). An obviousness analysis, however, is not a rigid formulaic analysis, but is a flexible determination grounded in the facts of the case. KSR International Co. v. Teleflex Inc., 127 St. Ct. 1727, 1739 (2007). Indeed, the common sense of those skilled in the art may demonstrate why some combinations are obvious and others are not. Leapfrog Enterprises, Inc. v. Fisher-Price, Inc., 485 F.3d 1157, 1161 (Fed. Cir. 2007).

In the present case, the Examiner has failed to establish a prima facie case of obviousness against the claims 21-27, 31, 36-39, and 42-49 because the combination of the Kaping Patent, the Kasdin Patent, the Cox Patent, and the Sipos Patent, (i) fails to teach each and every limitation of the claims, (ii) the Examiner has failed to establish any plausible rationale to justify the combination, and (iii) the Examiner has failed to establish that the combination would be enabling and/or that by

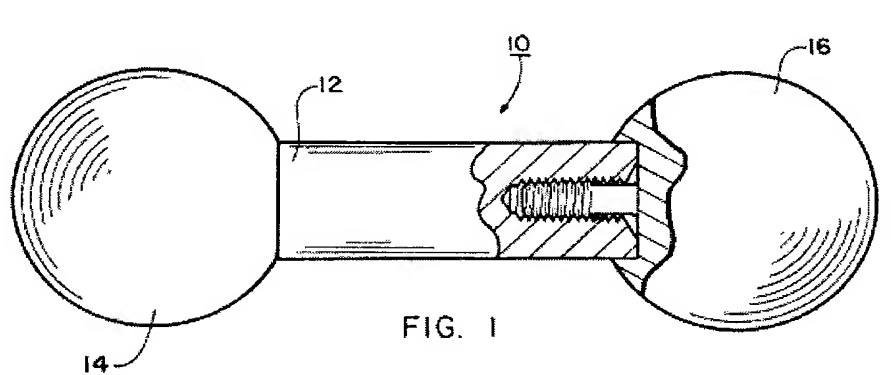
making the combination a person of ordinary skill in the art would have a reasonable expectation of arriving at the claimed invention. Appellant's position is explained in detail as follows.

**A. Claims 21-27, 31, 36-39, and 42-49**

The following general arguments pertain to independent claims 21, 31, 36-39, 44 and 45, and to dependent claims 22-27, 42, 43 and 46-49.

**i. The Kaping Patent**

U.S. Patent 6,026,659, the Kaping Patent, discloses a "body jewelry device and method of making the same," wherein, as shown in Figure 1, the body jewelry device (10) includes a post (12) with cap (14) coupled to one end of the post (12) and cap (16) coupled to the other end of the post (12), (See Kaping Patent, col. 3, lines 38-42). Figure 1 of the Kaping Patent is reproduced below. The Kaping Patent, at col. 3, lines 43-44, discloses that the post (12) is disposed in the pieced passageway in a wearer's tongue.



As admitted by the Examiner (Office Action, dated March 10, 2010, at 3, lines 7-12, and at 5, lines 14-19, and at 7, lines 14-19; Office Action, dated November 11, 2006, at 3, lines 18-21; Office Action, dated March 24, 2008, at 18-24; Office Action, dated November 26, 2008, at 3, lines 18-24), the Kaping Patent does not teach, or suggest, (i) "providing a mouth and tongue stud including a means for dispensing a substance formed in a portion of the stud" as recited by independent claims 21, 31, 36, 37, 38, 39, 44 and 45, (ii) "dispensing the substance into the wearer's mouth, wherein the

substance is dispensed...solely by dissolving the substance over time in the wearer's saliva" as recited by independent claims 21 and 31, (iii) "dispensing the substance into the wearer's mouth" as recited by independent claims 36, 38 and 39, (iv) "dispensing the medication into the wearer's mouth" as recited by independent claim 37, and (v)

"dispensing the substance into the wearer's mouth, wherein the substance has a form selected from the group consisting of a solid form and a tablet form,"

as recited by independent claims 44 and 45.

## ii. The Kasdin Patent

The Kasdin Patent discloses a "denture with a receptacle therein" as shown in Figures 1 and 2 that are reproduced below. As shown in Figures 1 and 2 of the Kasdin Patent, and upper denture includes a palate section (10), a flange portion (11) and false teeth (13), wherein a cup (15) is built into the flange portion (11), (Kasdin Patent, col. 1, line 57, to col. 2, line 11). A pill (21) may be placed in the cup (15) of the upper denture, and secured in place by a cap (17) provide with apertures (20) and a hinge post (18) so that saliva may reach the pill and be sweetened by the essence of the pill

FIG. 1

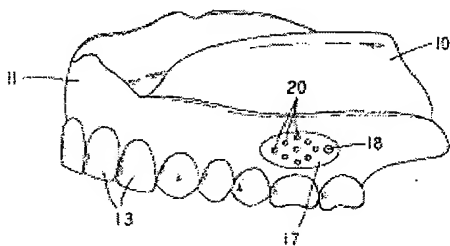
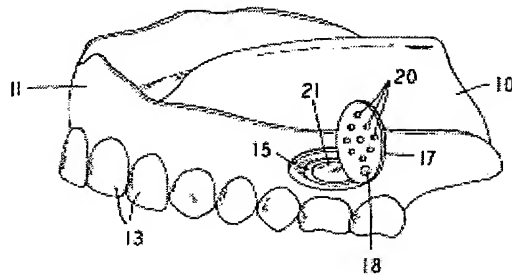


FIG. 2



Figures 1 and 2 of the Kasdin Patent

(Kasdin Patent, col. 2, lines 11-59)

However, the Kasdin Patent does not teach, or even suggest, (i) "providing a mouth and tongue stud including a means for dispensing a substance formed in a portion of the stud" as recited by independent claims 21, 31, 36, 37, 38, 39, 44 and 45. Furthermore, the Kasdin Patent does not

teach, or even suggest, (ii)

“dispensing the substance into the wearer’s mouth, wherein the substance is dispensed on or below, or on and below, the wearer’s tongue solely by dissolving the substance over time in the wearer’s saliva so that the dissolved substance is free to flow from the means for dispensing to on or below, or on and below, the wearer’s tongue,”

as recited by claims 21 and 31, (iii)

“dispensing the substance into the wearer’s mouth, wherein the substance is dispensed on or below, or on and below, the wearer’s tongue solely by dissolving the substance over time in the wearer’s saliva,”

as recited by claim 36, (iv)

“dispensing the medication into the wearer’s mouth, wherein the medication is dispensed on or below, or on and below, the wearer’s tongue solely by dissolving the medication over time in the wearer’s saliva,”

as recited by claim 37, (v)

“dispensing the substance into the wearer’s mouth, wherein the substance is dispensed into the wearer’s mouth on or below, or on and below, the wearer’s tongue by diffusing the substance from the stud into the wearer’s mouth over time in the wearer’s saliva,”

as recited by claims 38 and 39, and (vi)

“dispensing the substance into the wearer’s mouth, wherein the substance has a form selected from the group consisting of a solid form and a tablet form and is dispensed on or below, or on and below, the wearer’s tongue by dissolving the substance from the stud to flow on or below, or on and below, the wearer’s tongue over time in the wearer’s saliva,”

as recited by claims 44 and 45.

As shown in Figures 1 and 2 of the Kasdin Patent, the location of the cup (15) on the exterior, buccal surface of the dentures is such that the chemicals flowing from the pill (21) in cup (15) would be dispensed to the labial or buccal mucosa of the mouth (i.e., between the cheek and gums), and would not be “dispensed on or below, or on and below, the wearer’s tongue” as recited by independent claims 21, 31, 36, 37, 44 and 45, and it would not be “dispensed into the wearer’s mouth on or below, or on and below, the wearer’s tongue” as recited by independent claims 38 and 39. In fact, the Kasdin Patent teaches away from dispensing the sweet chemical on or below, or on and

below, the tongue because the Kasdin Patent discloses dispensing the sweet chemical at a location remote to the tongue and in a direction away from the tongue as would be inherent to the location of the cup (15) on the exterior buccal surface of the denture. See Continental Can Co. USA Inc. v. Monsanto Co., 20 U.S.P.Q.2d 1746, 1749 (Fed. Cir. 1991).

**a. The Kasdin Patent is Non-analogous Art**

The subject matter disclosed by the Kasdin Patent pertains to “dentures,” which is non-analogous art. A reference is non-analogous art if it is not from the same field of endeavor (i.e., the invention and the prior art device are not similar in structure and function), and if the reference is outside the inventor’s field of endeavor, the reference is non-analogous art only if the reference is not reasonably pertinent to the particular problem with which the inventor is involved. State Contracting & Engineering Corp. v. Condotte America, Inc., 346 F.3d 1057, 1069 (Fed. Cir. 2003). In this case, the Kasdin Patent pertains to “dentures” (Kasdin Patent, col. 1, lines 13-14), which have a substantially different structure and function than the subject matter of the present invention, which pertains to the field of “mouth and tongue studs” (i.e., oral body piercings). The fact that Kasdin’s dentures have a different structure from a “mouth and tongue stud” is evident by comparing Kasdin’s Figs. 1 and 2 with Applicant’s original Figs. 1-10. In addition, the function of dentures is to provide artificial replacement teeth, whereas the function of a “mouth and tongue stud” is to provide oral ornamentation and to enhance human sexual activities (See Applicant’s specification, at 2, lines 16-22). Therefore, it is a fact that Kasdin’s “dentures” pertains to the field of dentures and false teeth, which is a substantially different field of endeavor than that of the present invention, which pertains to the field of oral piercings. In fact, a person of ordinary skill in the art would immediately realize that the field of dentures and false teeth has absolutely nothing to do whatsoever with the field of oral body piercings.

In addition, the subject matter of the Kasdin Patent is not reasonably pertinent to the

particular problem with which the present invention has addressed. In particular, the present invention involves providing a mouth and tongue stud including a means for dispensing a substance, wherein the means for dispensing a substance is used to dispense the substance to the tongue and sublingual regions of the mouth (i.e., “the substance is dispensed on or below, or on and below, the wearer’s tongue” as recited by Applicant’s independent claims), (See, e.g., Applicants’ specification, at 2, lines 16, to 3, line 2). In other words, the problem faced by the inventor of the present invention was how to dispense a substance to the lingual and/or sublingual regions of the tongue. The device and methods disclosed by the Kasdin Patent have absolutely nothing to do whatsoever with dispensing a substance to the lingual and/or sublingual regions of the tongue.

The Kasdin Patent involves the use of a modified denture, and not to the use of a modified mouth and tongue stud, and the problem the Kasdin Patent addresses does not include how to dispense a substance to the tongue or sublingual regions of the mouth. On the contrary, the Kasdin Patent implicitly solves the problem regarding how to dispense a substance to buccal mucosa of the outer regions of the mouth (See Kasdin Patent, Figs. 1 and 2), which is a region remote from the tongue. As is known by those of ordinary skill in the art, the administration of many substances lingually and/or sublingually, such as medicines and the like, is substantially different from administration of medicines and the like to other regions of the mouth (See, e.g., <http://www.enotes.com/nursing-encyclopedia/sublingual-buccal-medication-administration>, last visited January 17, 2011). Therefore, it is clear that the Kasdin Patent is not reasonably pertinent to the particular problem the inventor of the present invention faced and addressed, which is how to dispense a substance to the lingual and/or sublingual regions of the mouth.

**Because the subject matter disclosed by the Kasdin Patent pertains to a substantially different field of endeavor than that of the presently claimed invention, and because the subject matter disclosed by the Kasdin Patent is not reasonably pertinent to the particular problem with which the present invention is involved, Applicant has shown that the Kasdin Patent is non-analogous art with respect to the subject matter of the claimed invention.**



The Examiner contends that the Kasdin denture is analogous art because “[it] is used in a wearer’s mouth, to dispense a substance into a wearer’s mouth” (Office Action, dated August 19, 2010, at 11, lines 14-15). The Examiner’s contention is flawed because one should look to the structure and function of devices to determine whether they are in the same field of endeavor. State Contracting & Engineering Corp. v. Condotte America, Inc., 346 F.3d 1057, 1069 (Fed. Cir. 2003). In this case, Kasdin’s dentures have a substantially different structure and function than a “mouth and tongue stud” as claimed. More specifically, the dentures are configured to fit over the wearer’s gums, and function to provide false teeth for chewing, etc. On the other hand, a “mouth and tongue stud” is a piece of body jewelry that is provided with a bar so the stud can be placed in the fistula of a pierced tongue, for example. A mouth and tongue stud does not mimic teeth in any way. A mouth and tongue stud serves primarily an ornamental purpose, although it may also be used to enhance human sexual experiences pertaining to fellatio and/or cunnilingus. Dentures are not related to piercings, and they are not generally associated with enhancing sexual pleasure.

In view of the fact that Kasdin’s dentures and the claimed mouth and tongue stud have completely different structures and functions, it is plainly evident that they do not pertain to the same field of endeavor. With respect to the Examiner’s contention that both Kasdin’s dentures and the claimed mouth and tongue stud dispense a substance into the mouth of the wearer, this is an overly broad characterization of the function that the two devices possess. As discussed above, Kasdin’s dentures dispense the substance to the buccal mucosa of the mouth and away from the tongue, whereas the claimed mouth and tongue stud dispenses the substance “on or below, or on and below, the wearer’s tongue.” Thus, while Kasdin’s modified dentures and Applicant’s mouth and tongue stud both dispense substances into a wearer’s mouth, they dispense the substances to substantially different portions of the mouth that are remote from one another and that are recognized, in the art, as being substantially different routes of administration (See, e.g., <http://www.enotes.com/nursing-encyclopedia/sublingual-buccal-medication-administration>, last visited January 17, 2011). The Kasdin dentures serve to administer a substance to the buccal mucosa, whereas the presently claimed

mouth and tongue stud and corresponding method pertain to the sublingual and/or lingual administration of the substance. Therefore, Kasdin's dentures and the presently claimed mouth and tongue stud function to dispense substances into the wearer's mouth in a substantially different way. Consequently, their functions are actually substantially different.

For all of the above reasons, Kasdin's dentures pertain to a substantially different field of endeavor than the presently claimed mouth and tongue stud. In addition, because Kasdin's dentures are used to dispense a substance to the buccal mucosa, which is remote from the tongue, Kasdin's device and method are not reasonably pertinent to the problem faced by the present inventor, which was how to administer a substance to the tongue and/or sublingual regions of a wearer's mouth.

For all of the above reasons, the Board should conclude that the Kasdin Patent is non-analogous art.

### **iii. The Cox Patent**

The Cox Patent discloses an "applicator for dispensing active substances," as shown in Figures 1, 2, 11, 12 and 13, for example. According to the Cox Patent, the oral applicator for the application of an active substance is in the form of a hollow structure corresponding substantially in shape and dimensions to an external form of a crown (2) of one or more natural teeth and adapted to contain the active substance, wherein the hollow structure (4) has one or more passage openings (5) for the controlled release of certain amounts of the active substance, wherein the passage openings (5) are formed in a buccal and/or palatal or lingual portion of the crown (5) for the passage of saliva and of the active substance dissolved therein (See Abstract of the Cox Patent, and col. 5, lines 15-68).

However, the Cox Patent does not teach, or even suggest, (i) "providing a mouth and tongue stud including a means for dispensing a substance formed in a portion of the stud" as recited by independent claims 21, 31, 36, 37, 38, 39, 44 and 45. Furthermore, the Cox Patent does not teach, or even suggest, (ii)

"dispensing the substance into the wearer's mouth, wherein the

substance is dispensed on or below, or on and below, the wearer's tongue solely by dissolving the substance over time in the wearer's saliva so that the dissolved substance is free to flow from the means for dispensing to on or below, or on and below, the wearer's tongue,"

as recited by claims 21 and 31, (iii)

"dispensing the substance into the wearer's mouth, wherein the substance is dispensed on or below, or on and below, the wearer's tongue solely by dissolving the substance over time in the wearer's saliva,"

as recited by claim 36, (iv)

"dispensing the medication into the wearer's mouth, wherein the medication is dispensed on or below, or on and below, the wearer's tongue solely by dissolving the medication over time in the wearer's saliva,"

as recited by claim 37, (v)

"dispensing the substance into the wearer's mouth, wherein the substance is dispensed into the wearer's mouth on or below, or on and below, the wearer's tongue by diffusing the substance from the stud into the wearer's mouth over time in the wearer's saliva,"

as recited by claims 38 and 39, and (vi)

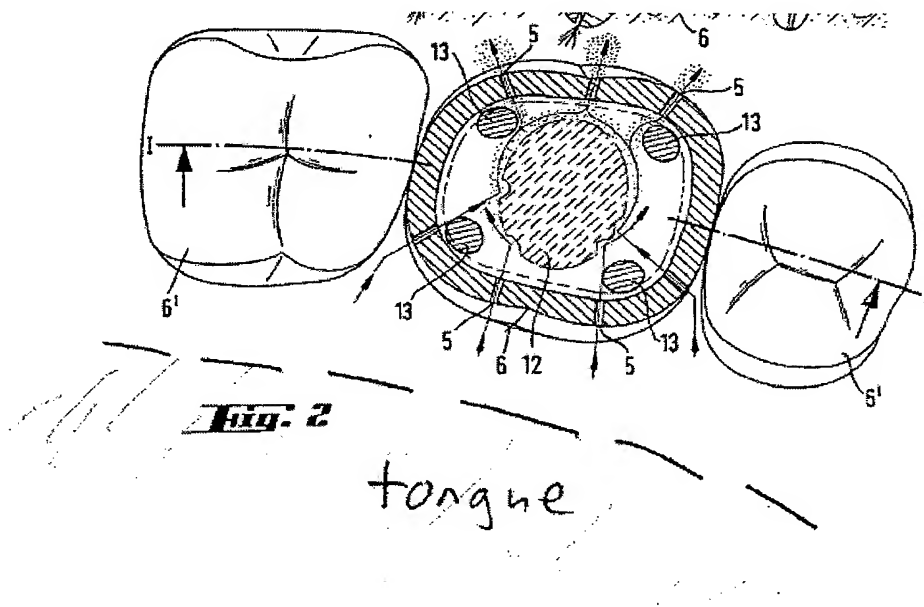
"dispensing the substance into the wearer's mouth, wherein the substance has a form selected from the group consisting of a solid form and a tablet form and is dispensed on or below, or on and below, the wearer's tongue by dissolving the substance from the stud to flow on or below, or on and below, the wearer's tongue over time in the wearer's saliva,"

as recited by claims 44 and 45.

As shown in Figures 2, 11 and 13 of the Cox Patent, the flow of saliva through openings (5) on the lingual side of the crown (2) and out the openings (5) on the buccal side of the crown (2) is such that the substance is dispensed on the buccal side of the crown (2) and not on the lingual side of the crown (2), (Cox Patent, col. 6, lines 7-13). This fact is evident from the size and curvature of the teeth, and progression of teeth from molars to premolars (See, e.g., GRAY'S ANATOMY 1413-1417 and 1432 (Carmin D. Clemente ed., Lea & Fabringer 1985), a copy of which is of record as "Exhibit AD"), from which a person of ordinary skill in the art can deduce where the location of the tongue would be in the figures of the Cox Patent. To aid visualization of where the tongue is located relative to the other structures in Figures 2, 11 and 13, Applicant provides below annotated versions of

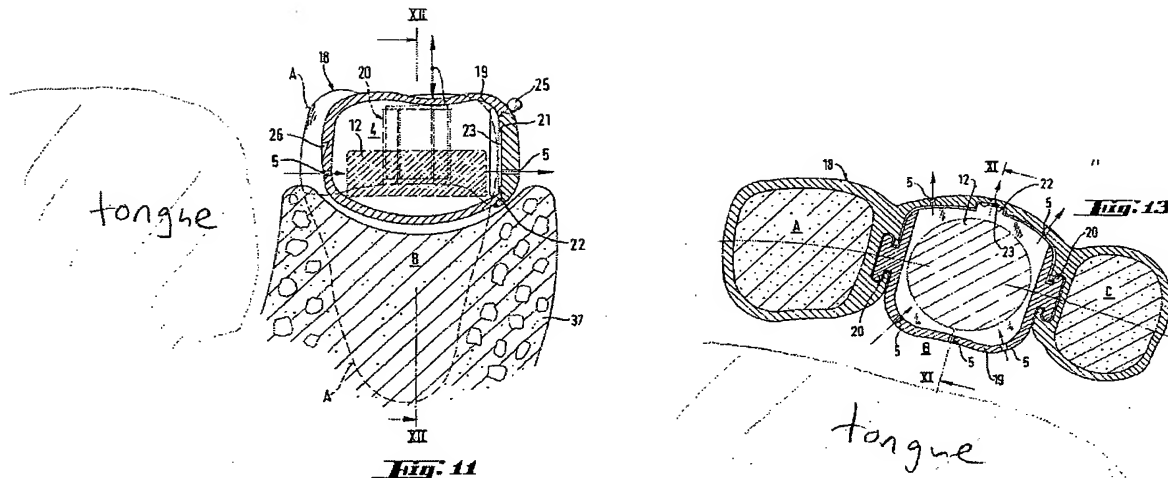
Figures 2, 11 and 13 of the Cox Patent.

As evident from annotated Figures 2, 11 and 13 of the Cox Patent, the flow of saliva as shown by the arrows passing through openings (5) is away from the tongue. Consequently, any substance dispensed from the hollow chamber (4) of the crown (2) is dispensed on the buccal side of the teeth and is directed away from the tongue. In other words, the substance flowing from the hollow chamber (4) through openings (5) of the crown (2) would be dispensed to the buccal mucosa of the mouth, and would not be "dispensed on or below, or on and below, the wearer's tongue" as recited by independent claims 21, 31, 36, 37, 44 and 45, and it would not be "dispensed into the wearer's mouth on or below, or on and below, the wearer's tongue" as recited by independent claims 38 and 39. In fact, the Cox Patent teaches away from dispensing the substance on or below, or on



Annotated Figure 2 of Cox Patent

and below, the tongue because the Cox Patent discloses dispensing the substance at a location remote to the tongue and in a direction away from the tongue as is evident from the direction of saliva flow illustrated through openings (5) of the crown (2) in annotated Figures 2, 11 and 13 of the Cox Patent.



Annotated Figures 11 and 13 of the Cox Patent

**a. The Cox Patent is Non-analogous Art**

The subject matter disclosed by the Cox Patent pertains to a modified crown for a tooth, which pertains to non-analogous art. A reference is non-analogous art if it is not from the same field of endeavor (i.e., the invention and the prior art device are not similar in structure and function), and if the reference is outside the inventor's field of endeavor, the reference is non-analogous art only if the reference is not reasonably pertinent to the particular problem with which the inventor is involved. State Contracting & Engineering Corp. v. Condotte America, Inc., 346 F.3d 1057, 1069 (Fed. Cir. 2003). In this case, the Cox Patent pertains to a dental crown for a tooth (Cox Patent, col. 2, lines 33-38), which has a substantially different structure and function than the subject matter of the present invention, which pertains to the field of "mouth and tongue studs" (i.e., oral body piercings).

More specifically, a dental crown is configured to fit over a wearer's tooth, and it functions to provide a tooth-shaped "cap" that is placed over the tooth to restore its shape and size, strength, and/or to improve its appearance as is known by persons of ordinary skill in the art (See, e.g., <http://www.webmd.com/oral-health/dental-crowns>, last visited January 17, 2011). On the other hand, a "mouth and tongue stud" is a piece of body jewelry that is provided with a bar so the stud can be placed in the fistula of a pierced tongue, for example. A mouth and tongue stud does not mimic teeth

in any way. A mouth and tongue stud serves primarily an ornamental purpose, although it may also be used to enhance human sexual experiences pertaining to fellatio and/or cunnilingus. Dental crowns and implants are not related to piercings in any way whatsoever, and they are not generally associated with enhancing sexual pleasure.

The fact that Cox's crown has a different structure from a "mouth and tongue stud" is evident by comparing Cox's Figs. 2, 11 and 13 with Applicant's original Figs. 1-10. In addition, the function of the crown is to repair damaged teeth (Cox Patent, col. 3, lines 26-65; and col. 5, lines 15-35), whereas the function of a "mouth and tongue stud" is to provide oral ornamentation and to enhance human sexual activities (See Applicant's specification, at 2, lines 16-22). Therefore, Cox's dental "crown" and method for dispensing substances from the dental crown onto the buccal mucosa of the mouth (i.e., between the cheek and gums) pertain to a substantially different field of endeavor than that of the present invention, which pertains to a "mouth and tongue stud" and a method for dispensing a substance on or above, or on and above, the tongue of the mouth. In fact, a person of ordinary skill in the art would immediately realize that the field of dental crowns and implants has absolutely nothing to do whatsoever with the field of oral body piercings.

In addition, the subject matter of the Cox Patent is not reasonably pertinent to the particular problem with which the present inventor has addressed. In particular, the present invention involves providing a mouth and tongue stud including a means for dispensing a substance, wherein the means for dispensing a substance is used to dispense the substance to the tongue and sublingual regions of the mouth (i.e., "the substance is dispensed...on or below, or on and below, the wearer's tongue" as recited by Applicant's independent claims), (See, e.g., Applicants' specification, at 2, lines 16, to 3, line 2). The device and methods disclosed by the Cox Patent involve the use of a modified dental crown or implant, and not to the use of a mouth and tongue stud, and the problem the Cox Patent addresses does not include how to dispense a substance to the tongue or sublingual regions of the mouth. Therefore, the Cox Patent is not reasonably pertinent to the particular problem the inventor of the subject matter of the above-captioned application faced and addressed. In fact, the device and

methods disclosed by the Cox Patent have absolutely nothing to do whatsoever with dispensing a substance to the lingual and/or sublingual regions of the tongue.

The Cox Patent involves the use of a modified dental crown or implant, and not to the use of a modified mouth and tongue stud, and the problem the Cox Patent addresses does not include how to dispense a substance to the tongue or sublingual regions of the mouth. On the contrary, the Cox Patent implicitly solves the problem regarding how to dispense a substance to the buccal mucosa of the outer regions of the mouth as discussed above (See Cox Patent, Figs. 2, 11 and 13; and col. 6, lines 7-13), which is a region remote from the tongue, and in a direction away from the tongue. As is known by those of ordinary skill in the art, the administration of many substances lingually and/or sublingually, such as medicines and the like, is substantially different from administration of medicines and the like to other regions of the mouth such as the buccal mucosa (See, e.g., <http://www.enotes.com/nursing-encyclopedia/sublingual-buccal-medication-administration>, last visited January 17, 2011). Therefore, it is clear that the Cox Patent is not reasonably pertinent to the particular problem the inventor of the present invention faced and addressed, which is how to dispense a substance to the lingual and/or sublingual regions of the mouth.

**Because the subject matter disclosed by the Cox Patent pertains to a substantially different field of endeavor than that of the presently claimed invention, and because the subject matter disclosed by the Cox Patent is not reasonably pertinent to the particular problem with which the present invention is involved, Applicant has shown that the Cox Patent is non-analogous art with respect to the subject matter of the claimed invention.**

The Examiner contends that the Cox dental crown is analogous art because “[it] is used in a wearer’s mouth, to dispense a substance into a wearer’s mouth” (Office Action, dated August 19, 2010, at 11, lines 14-15). The Examiner’s contention is flawed because one should look to the structure and function of devices to determine whether they are in the same field of endeavor. State Contracting & Engineering Corp. v. Condotte America, Inc., 346 F.3d 1057, 1069 (Fed. Cir. 2003). In this case, Cox’s dental crown has a substantially different structure and function than a “mouth and

tongue stud” as claimed. More specifically, the dental crown is configured to fit over the wearer’s tooth, and functions to restore the shape, size and appearance of the tooth (Cox Patent, col.3, lines 26-65; and col. 5, lines 10-35). On the other hand, a “mouth and tongue stud” is a piece of body jewelry that is provided with a bar so the stud can be placed in the fistula of a pierced tongue, for example. A mouth and tongue stud does not mimic a tooth in any way. A mouth and tongue stud serves primarily an ornamental purpose, although it may also be used to enhance human sexual experiences pertaining to fellatio and/or cunnilingus. A dental crown or implant is not related to piercings, and it is not generally associated with enhancing sexual pleasure.

In view of the fact that Cox’s dental crown and the claimed mouth and tongue stud have completely different structures and functions, it is plainly evident that they do not pertain to the same field of endeavor. With respect to the Examiner’s contention that both Cox’s dental crown and the claimed mouth and tongue stud dispense a substance into the mouth of the wearer, this is an overly broad characterization of the function that the two devices possess. As discussed above, Cox’s dental crown dispenses the substance to the buccal mucosa of the mouth and away from the tongue (Cox Patent, col. 6, lines 7-13; and Figs. 2, 11 and 13), whereas the claimed mouth and tongue stud dispenses the substance “on or below, or on and below, the wearer’s tongue.” Thus, while Cox’s modified dental crown and Applicant’s mouth and tongue stud both dispense substances into a wearer’s mouth, they dispense the substances to substantially different portions of the mouth that are remote from one another and that are recognized, in the art, as being substantially different routes of administration (See, e.g., <http://www.enotes.com/nursing-encyclopedia/sublingual-buccal-medication-administration>, last visited January 17, 2011). The Cox’s dental crown serves to administer a substance to the buccal mucosa, whereas the presently claimed mouth and tongue stud and corresponding method pertain to the sublingual and/or lingual administration of the substance. Therefore, Cox’s dental crown and the presently claimed mouth and tongue stud function to dispense substances into the wearer’s mouth in a substantially different way. Consequently, their functions are actually substantially different.

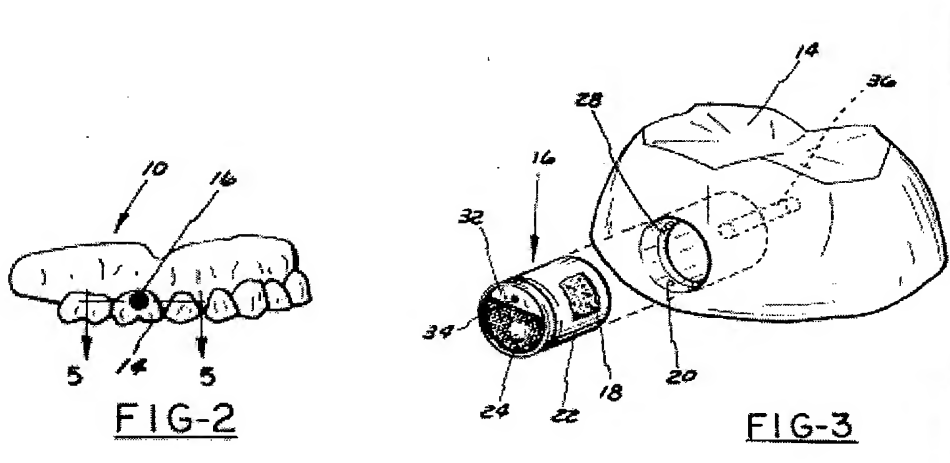


For all of the above reasons, Cox's dental crown or implant pertains to a substantially different field of endeavor than the presently claimed mouth and tongue stud. In addition, because Cox's dental crown is used to dispense a substance to the buccal mucosa, which is remote from the tongue, Cox's device and method are not reasonably pertinent to the problem faced by the present inventor, which was how to administer a substance to the tongue and/or sublingual regions of a wearer's mouth.

For all of the above reasons, the Board should conclude that the Cox Patent is non-analogous art.

#### iv. The Sipos Patent

The Sipos Patent discloses an "odiferous dental apparatus" as shown in Figures 2 and 3, which are reproduced below for convenience. According to the Sipos Patent, an oral apparatus for making the mouth pleasantly tasteful and exhaled air aromatically pleasant is provided in an artificial tooth (14) or other dental appliance (i.e., dentures) and includes an opening (20) therein filled with either absorbent fibrous material (18) saturated with an air-refreshant fluid or a removable insert (16) for containing such fluid (See Abstract of the Sipos Patent, col. 2, lines 13-74).



Figures 2 and 3 of the Sipos Patent

However, the Sipos Patent does not teach, or even suggest, (i) "providing a mouth and tongue stud including a means for dispensing a substance formed in a portion of the stud" as recited by

independent claims 21, 31, 36, 37, 38, 39, 44 and 45. Furthermore, the Sipos Patent does not teach, or even suggest, (ii)

“dispensing the substance into the wearer’s mouth, wherein the substance is dispensed on or below, or on and below, the wearer’s tongue solely by dissolving the substance over time in the wearer’s saliva so that the dissolved substance is free to flow from the means for dispensing to on or below, or on and below, the wearer’s tongue,”

as recited by claims 21 and 31, (iii)

“dispensing the substance into the wearer’s mouth, wherein the substance is dispensed on or below, or on and below, the wearer’s tongue solely by dissolving the substance over time in the wearer’s saliva,”

as recited by claim 36, (iv)

“dispensing the medication into the wearer’s mouth, wherein the medication is dispensed on or below, or on and below, the wearer’s tongue solely by dissolving the medication over time in the wearer’s saliva,”

as recited by claim 37, (v)

“dispensing the substance into the wearer’s mouth, wherein the substance is dispensed into the wearer’s mouth on or below, or on and below, the wearer’s tongue by diffusing the substance from the stud into the wearer’s mouth over time in the wearer’s saliva,”

as recited by claims 38 and 39, and (vi)

“dispensing the substance into the wearer’s mouth, wherein the substance has a form selected from the group consisting of a solid form and a tablet form and is dispensed on or below, or on and below, the wearer’s tongue by dissolving the substance from the stud to flow on or below, or on and below, the wearer’s tongue over time in the wearer’s saliva,”

as recited by claims 44 and 45.

As shown in Figures 2 and 3 of the Sipos Patent, the location of the opening (20) on the exterior, buccal surface of the dentures is such that the fluids flowing from the insert (16) in opening (20) would be dispensed to the labial or buccal mucosa of the mouth, and would not be “dispensed on or below, or on and below, the wearer’s tongue” as recited by independent claims 21, 31, 36, 37, 44 and 45, and it would not be “dispensed into the wearer’s mouth on or below, or on and below, the wearer’s tongue” as recited by independent claims 38 and 39. In fact, the Sipos Patent teaches away

from dispensing the fluids on or below, or on and below, the tongue because the Sipos Patent discloses dispensing the fluids at a location remote to the tongue and in a direction away from the tongue as would be inherent to the location of the insert (16) on the exterior buccal surface of the denture. See Continental Can Co. USA Inc. v. Monsanto Co., 20 U.S.P.Q.2d 1746, 1749 (Fed. Cir. 1991).

**a. The Sipos Patent is Non-analogous Art**

The subject matter disclosed by the Sipos Patent pertains to “dentures” (Sipos Patent, col. 2, lines 12-14), which pertains to non-analogous art. A reference is non-analogous art if it is not from the same field of endeavor (i.e., the invention and the prior art device are not similar in structure and function), and if the reference is outside the inventor’s field of endeavor, the reference is non-analogous art only if the reference is not reasonably pertinent to the particular problem with which the inventor is involved. State Contracting & Engineering Corp. v. Condotte America, Inc., 346 F.3d 1057, 1069 (Fed. Cir. 2003). In this case, the Sipos Patent pertains to “dentures” and an “artificial tooth” (Sipos Patent, col. 1, lines 59-61 and lines 64-65; and Figs. 1 and 3), which have a substantially different structure and function than the subject matter of the present invention, which pertains to the field of “mouth and tongue studs” (i.e., oral body piercings). The fact that Sipos’s dentures and artificial tooth each have a different structure from a “mouth and tongue stud” is evident by comparing Sipos’s Figs. 1 and 3 with Applicant’s original Figs. 1-10. In addition, the function of dentures or an artificial tooth is to provide artificial replacement teeth, whereas the function of a “mouth and tongue stud” is to provide oral ornamentation and to enhance human sexual activities (See Applicant’s specification, at 2, lines 16-22). Therefore, it is a fact that Sipos’s “dentures” and “artificial tooth” pertain to the field of dentures and false teeth, which is a substantially different field of endeavor than that of the present invention, which pertains to the field of oral piercings. In fact, a person of ordinary skill in the art would immediately realize that the field of dentures and false teeth has absolutely nothing to do whatsoever with the field of oral body piercings.

In addition, the subject matter of the Sipos Patent is not reasonably pertinent to the particular problem with which the present invention has addressed. In particular, the present invention involves providing a mouth and tongue stud including a means for dispensing a substance, wherein the means for dispensing a substance is used to dispense the substance to the tongue and sublingual regions of the mouth (i.e., “the substance is dispensed...on or below, or on and below, the wearer’s tongue” as recited by Applicant’s independent claims), (See, e.g., Applicants’ specification, at 2, lines 16, to 3, line 2). In other words, the problem faced by the inventor of the present invention was how to dispense a substance to the lingual and/or sublingual regions of the tongue. The device and methods disclosed by the Sipos Patent have absolutely nothing to do whatsoever with dispensing a substance to the lingual and/or sublingual regions of the tongue.

The Sipos Patent involves the use of a modified denture or modified artificial tooth, and not to the use of a modified mouth and tongue stud, and the problem the Sipos Patent addresses does not include how to dispense a substance to the tongue or sublingual regions of the mouth. On the contrary, the Sipos Patent implicitly solves the problem regarding how to dispense a substance to buccal mucosa of the outer regions of the mouth (See Sipos Patent, Figs. 1 and 3; and col. 2, lines 16-17), which is a region remote from the tongue. In particular, the placement of dental insert (16) in the upper denture (10) places the insert between the gum and the cheek of the wearer so that any substance dispensed is dispensed to the buccal mucosa side (Sipos Patent, col. 2, lines 19-20), and away from the wearer’s tongue and sublingual regions. Likewise, the placement of the insert (16) on the convex face of the artificial tooth (14) suggests its placement on the buccal surface of the tooth (Sipos Patent, col. 2, lines 20-25; and Fig. 3).

As is known by those of ordinary skill in the art, the administration of many substances lingually and/or sublingually, such as medicines and the like, is substantially different from administration of medicines and the like to other regions of the mouth (See, e.g., <http://www.enotes.com/nursing-encyclopedia/sublingual-buccal-medication-administration>, last visited January 17, 2011). Therefore, it is clear that the Sipos Patent is not reasonably pertinent to

the particular problem the inventor of the present invention faced and addressed, which is how to dispense a substance to the lingual and/or sublingual regions of the mouth.

**Because the subject matter disclosed by the Sipos Patent pertains to a substantially different field of endeavor than that of the presently claimed invention, and because the subject matter disclosed by the Sipos Patent is not reasonably pertinent to the particular problem with which the present invention is involved, Applicant has shown that the Sipos Patent is non-analogous art with respect to the subject matter of the claimed invention.**

The Examiner contends that the Sipos denture and artificial tooth is analogous art because “[it] is used in a wearer’s mouth, to dispense a substance into a wearer’s mouth” (Office Action, dated August 19, 2010, at 11, lines 14-15). The Examiner’s contention is flawed because one should look to the structure and function of devices to determine whether they are in the same field of endeavor. State Contracting & Engineering Corp. v. Condotte America, Inc., 346 F.3d 1057, 1069 (Fed. Cir. 2003). In this case, Sipos’s dentures and artificial tooth have a substantially different structure and function than a “mouth and tongue stud” as claimed. More specifically, the dentures are configured to fit over the wearer’s gums, and function to provide false teeth for chewing, etc, and the artificial tooth is a replacement tooth (Sipos Patent, col. 4, lines 6-16). On the other hand, a “mouth and tongue stud” is a piece of body jewelry that is provided with a bar so the stud can be placed in the fistula of a pierced tongue, for example. A mouth and tongue stud does not mimic teeth in any way. A mouth and tongue stud serves primarily an ornamental purpose, although it may also be used to enhance human sexual experiences pertaining to fellatio and/or cunnilingus. Dentures and/or a false tooth are not related to piercings, and they are not generally associated with enhancing sexual pleasure.

In view of the fact that Sipos’s dentures and artificial tooth, and the claimed mouth and tongue stud, have completely different structures and functions, it is plainly evident that they do not pertain to the same field of endeavor. With respect to the Examiner’s contention that both Sipos’s dentures/artificial tooth and the claimed mouth and tongue stud dispense a substance into the mouth

of the wearer, this is an overly broad characterization of the function that the two devices possess. As discussed above, Sipos's dentures/false tooth dispenses the substance to the buccal mucosa of the mouth and away from the tongue, whereas the claimed mouth and tongue stud dispenses the substance "on or below, or on and below, the wearer's tongue." Thus, while Sipos's modified dentures/false tooth and Applicant's mouth and tongue stud both dispense substances into a wearer's mouth, they dispense the substances to substantially different portions of the mouth that are remote from one another and that are recognized, in the art, as being substantially different routes of administration (See, e.g., <http://www.enotes.com/nursing-encyclopedia/sublingual-buccal-medication-administration>, last visited January 17, 2011). The Sipos dentures/false tooth serves to administer a substance to the buccal mucosa, whereas the presently claimed mouth and tongue stud and corresponding method pertain to the sublingual and/or lingual administration of the substance. Therefore, Sipos's dentures/false tooth and the presently claimed mouth and tongue stud function to dispense substances into the wearer's mouth in a substantially different way. Consequently, their functions are actually substantially different.

For all of the above reasons, Sipos's dentures pertain to a substantially different field of endeavor than the presently claimed mouth and tongue stud. In addition, because Sipos's dentures are used to dispense a substance to the buccal mucosa, which is remote from the tongue, Sipos's device and method are not reasonably pertinent to the problem faced by the present inventor, which was how to administer a substance to the tongue and/or sublingual regions of a wearer's mouth.

For all of the above reasons, the Board should conclude that the Sipos Patent is non-analogous art.

#### **v. Summary of the Disclosures**

The Kaping Patent discloses a conventional bar bell stud that is inserted through a passageway in a user's tongue. The Kaping Patent does not teach, or suggest, any "means for dispensing a substance" and/or any related features thereof.

The Kasdin Patent and the Sipos Patent each disclose dentures modified to dispense a chemical or liquid to the labial or buccal mucosa of the mouth, and away from the tongue. Neither the Kasdin Patent nor the Sipos Patent teach, or suggest, a “mouth and tongue stud including a means for dispensing a substance” as claimed. In fact, the Kasdin Patent and the Sipos Patent are non-analogous art with respect to the subject matter of the presently claimed invention, and each teaches away from using a device to dispense a substance on or below, or on and below, the wearer’s tongue solely by dissolving the substance over time in the wearer’s saliva.

The Cox Patent and the Sipos Patent each discloses a crown for a tooth (i.e., an artificial tooth), wherein the crown is modified to dispense a substance towards the buccal mucosa of the mouth, and away from the tongue. Neither the Cox Patent nor the Sipos Patent teach, or suggest, a “mouth and tongue stud including a means for dispensing a substance” as claimed. In fact, the Cox Patent and the Sipos Patent are non-analogous art with respect the subject matter of the presently claimed invention, and each teaches away from using a device to dispense a substance on or below, or on and below, the wearer’s tongue solely by dissolving the substance over time in the wearer’s saliva.

The combination of the disclosures of the Kaping Patent, the Kasdin Patent, the Cox Patent, and the Sipos Patent does not teach, or even suggest, (i) **“providing a mouth and tongue stud including a means for dispensing a substance formed in a portion of the stud”** as recited by independent claims 21, 31, 36, 37, 38, 39, 44 and 45, (ii)

**“dispensing the substance into the wearer’s mouth, wherein the substance is dispensed on or below, or on and below, the wearer’s tongue solely by dissolving the substance over time in the wearer’s saliva so that the dissolved substance is free to flow from the means for dispensing to on or below, or on and below, the wearer’s tongue,”**

as recited by claims 21 and 31, (iii)

**“dispensing the substance into the wearer’s mouth, wherein the substance is dispensed on or below, or on and below, the wearer’s tongue solely by dissolving the substance over time in the wearer’s saliva,”**

as recited by claim 36, (iv)

“dispensing the medication into the wearer’s mouth, wherein the medication is dispensed on or below, or on and below, the wearer’s tongue solely by dissolving the medication over time in the wearer’s saliva,”

as recited by claim 37, (v)

“dispensing the substance into the wearer’s mouth, wherein the substance is dispensed into the wearer’s mouth on or below, or on and below, the wearer’s tongue by diffusing the substance from the stud into the wearer’s mouth over time in the wearer’s saliva,”

as recited by claims 38 and 39, and (vi)

“dispensing the substance into the wearer’s mouth, wherein the substance has a form selected from the group consisting of a solid form and a tablet form and is dispensed on or below, or on and below, the wearer’s tongue by dissolving the substance from the stud to flow on or below, or on and below, the wearer’s tongue over time in the wearer’s saliva,”

as recited by claims 44 and 45.

For all of the above reasons, the Board should conclude that the Examiner has failed to establish a prima facie case of obviousness against claims 21-27, 31, 36-39, and 42-49 of the above-captioned application.

**vi. The Examiner’s Retrospective View of Inherency is Improper and Should be Withdrawn**

Applicant argued that neither the Kaping Patent, nor the Kasdin Patent, nor the Cox Patent, nor the Sipos Patent teaches, or suggests, “the substance is dispensed...on or below, or on and below, the wearer’s tongue” as recited by independent claims 21, 31, 36-39, 44 and 45 (See Amendment (K), filed July 12, 2010, at 24, line 5, to 25, line 24; and at 27, lines 8-19). The Examiner does not dispute that neither the Kaping Patent, nor the Kasdin Patent, nor the Cox Patent, nor the Sipos Patent discloses this feature. Therefore, the Examiner has conceded that neither the Kaping Patent, nor the Kasdin Patent, nor the Cox Patent, nor the Sipos Patent discloses this claimed limitation.

The Examiner contends that

“the primary reference, Kaping, Jr., is body jewelry device that is for use in a tongue of a wearer. This body jewelry device, as described above, is the reference that is modified with means for dispensing a substance. Since the body jewelry



device is already in use as a tongue stud, the newly submitted claim limitation of 'on or below, or on and below, the wearer's tongue' will thus be met."

(Office Action, mailed August 19, 2010, at 10, lines 10-15).

The Examiner's argument is an impermissible retrospective view of inherency, and must be withdrawn by the Board for the following reasons.

The Federal Circuit has ruled that a prima facie case of obviousness cannot be established based on a retrospective view of inherency because obviousness cannot be predicated on the unknown. In re Newell, 13 U.S.P.Q.2d 1248, 1250 (Fed. Cir. 1989)(Federal Circuit rejected USPTO's argument that a combination of the art would result in a device that would inherently have certain features because obviousness cannot be predicated on the unknown). In In re Newell, 13 U.S.P.Q.2d at 1249-50, the alleged obviousness rejection was based on a hypothetical construct, created by the Patent Office as a legal argument, by combining the disclosures of two or more prior art devices. The Patent Office then argued that this hypothetical device would inherently operate in a manner that none of the prior art documents actually disclosed. In re Newell, 13 U.S.P.Q.2d at 1250. The Federal Circuit vacated the obviousness rejection because such an obviousness rejection, based on alleged inherent features a hypothetical device might possess, was deemed an improper "retrospective view of inherency." In re Newell, 13 U.S.P.Q.2d at 1250. Thus, while the doctrine of inherency may be applied to a single prior art device, Continental Can Co. USA Inc. v. Monsanto Co., 20 U.S.P.Q.2d 1746, 1749 (Fed. Cir. 1991), the Federal Circuit refused to apply the doctrine to a hypothetical device created by the USPTO as a legal argument, In re Newell, 13 U.S.P.Q.2d at 1250. In other words, the doctrine of inherency applies only to actual prior art devices, and not to hypothetical devices that do not exist in the prior art, but that are merely legal arguments.

In this case, the Examiner admits that the Kaping Patent does not teach, or suggest, a means for dispensing a substance" (Office Action, mailed August 19, 2010, at 3, lines 3-8); therefore, the Kaping Patent also does not teach, or suggest, "the substance is dispensed...on or below, or on and below, the wearer's tongue" as recited by independent claims 21, 31, 36-39, 44 and 45. The Examiner further implicitly concedes that the Kasdin Patent, the Cox Patent, and the Sipos Patent

each disclose devices for dispensing a substance to the region between the cheek and gums of a wearer, which is the buccal side of the teeth, and not the lingual side of the teeth (See, e.g., Exhibit AD, at 1414, of record). Therefore, **it is a fact that neither the Kaping Patent, the Kasdin Patent, the Cox Patent, nor the Sipos Patent, disclose dispensing a substance on, or below, the tongue of a wearer.**

In view of the above facts, a prima facie case of obviousness cannot be supported by an allegation that the Examiner's hypothetical device, resulting from the combination of the Kaping Patent, the Kasdin Patent, the Cox Patent, and the Sipos Patent, would inherently operate to dispense a substance "on or below, or on and below, the wearer's tongue" because the Examiner's hypothetical device is not prior art, In re Newell, 13 U.S.P.Q.2d at 1250, and because the inherency doctrine may be applied only to the disclosure of a single prior art reference. Continental Can Co. USA Inc. v. Monsanto Co., 20 U.S.P.Q.2d at 1749.

For all of the above reasons, the Examiner's inherency argument is untenable and must be withdrawn by the Board, and the Board should conclude that the Examiner has failed to establish a prima facie case of obviousness against claims 21-27, 31, 36-39, and 42-49 of the above-captioned application.

**vii. The Examiner has Not Established a Prima Facie Case of Obviousness**  
**Because There is No Plausible Rationale to Justify Combining the Disclosures of**  
**the Kasdin Patent, the Cox Patent and the Sipos Patent with the Kaping Patent**

A proper rejection under Section 103 requires showing (1) that a person of ordinary skill in the art would have had a legitimate reason to attempt to make the composition or device, or to carry out the claimed process, and (2) that the person of ordinary skill in the art would have had a reasonable expectation of success in doing so. PharmaStem Therapeutics, Inc. v. ViaCell, Inc., 491 F.3d 1342, 1360 (Fed. Cir. 2007). Thus, an obviousness determination based on a combination of art must include a "plausible rationale" to justify the combination. Power-One, Inc. v. Artesyn Technologies,

Inc., 599 F.3d 1343, 1351-52 (Fed. Cir. 2010). In this case, the Examiner has failed to establish a proper teaching, motivation, suggestion, or any plausible rationale whatsoever, to justify combining the Kaping Patent's bar bell stud with the dentures, artificial tooth, and dental crowns disclosed by the Kasdin Patent, the Cox Patent, and/or the Sipos Patent for the following reasons.

First, while the Kaping Patent discloses a conventional bar bell stud for inserting into a tongue piercing, the conventional bar bell stud does not include any means for dispensing a substance. On the other hand, the Kasdin Patent discloses dentures, the Cox Patent discloses a dental crown or implant, and the Sipos Patent discloses dentures and an artificial tooth. Each one of the Kasdin Patent, the Cox Patent, and the Sipos Patent, pertains to non-analogous art as established above. It is a well-settled proposition that a prima facie case of obviousness cannot be based on non-analogous art. In re Clay, 23 U.S.P.Q.2d 1058, 1060-61 (Fed. Cir. 1992). Therefore, a person of ordinary skill in the art would have no legitimate reason whatsoever to make the combinations asserted by the Examiner, and, in view of the Federal Circuit's holding in In re Clay, 23 U.S.P.Q.2d at 1061, the Examiner's obviousness rejections must be withdrawn because they are all based on non-analogous art. Therefore, the Examiner has failed to establish a plausible rationale to justify the combination of art.

Second, each of the Kasdin Patent, the Cox Patent, and the Sipos Patent disclose methods for dispensing substances to the buccal mucosa of the mouth (i.e., between the cheek and gums) and away from the tongue. Therefore, each of the Kasdin Patent, the Cox Patent and the Sipos Patent actually teaches away from the presently claimed invention. It is a well-settled proposition that a prima facie case of obviousness cannot be based on prior art disclosures that actually teach away from the claimed invention. McGinley v. Franklin Sports Inc., 60 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 2001). Furthermore, disclosures that actually teach away from an applicant's invention are highly probative evidence of non-obviousness. Raytheon Corp. v. Roper Corp., 724 F.2d 951, 961 (Fed. Cir. 1983). Because the Kasdin Patent, the Cox Patent, and the Sipos Patent all disclose dispensing a substance to the buccal mucosa of the mouth, and away from the tongue, the Board should conclude

that these documents constitute probative evidence regarding the non-obviousness of Applicant's claimed invention. In other words, the fact that the art of record teaches away from the combination of art asserted by the Examiner is evidence that the Examiner has failed to establish a plausible rationale to justify the alleged combination of art. Power-One, Inc. v. Artesyn Technologies, Inc., 599 F.3d at 1351-52.

In sum, because the Kasdin Patent, the Cox Patent and the Sipos Patent are each non-analogous art with respect to the presently claimed invention, and/or because the Kasdin Patent, the Cox Patent, and the Sipos Patent each teach away from the claimed invention, the Board should conclude that the Examiner has failed to establish a prima facie case of obviousness against claims 21-27, 31, 36-39 and 42-49 of the above-captioned application because the Examiner has failed to establish a plausible rationale to justify the combination.

**viii. The Examiner has not Established a Prima Facie Case of Obviousness  
Because the Examiner Failed to Demonstrate a Reasonable Expectation of  
Success Even if the Combinations Proposed by the Examiner Were Made**

A proper rejection under Section 103 requires showing (1) that a person of ordinary skill in the art would have had a legitimate reason to attempt to make the composition or device, or to carry out the claimed process, and (2) that the person of ordinary skill in the art would have had a reasonable expectation of success in doing so. PharmaStem Therapeutics, Inc. v. ViaCell, Inc., 491 F.3d 1342, 1360 (Fed. Cir. 2007). In this case, assuming that the Examiner has established a plausible rationale to justify the combination of the Kaping Patent with the Kasdin Patent and/or the Cox Patent and/or the Sipos Patent (which is a completely invalid assumption), the Examiner has still failed to establish that a person of ordinary skill in the art would have had a reasonable expectation of success of arriving at the claimed invention if the combinations asserted by the Examiner were made.

Specifically, the Cox Patent discloses modifying a dental crown or implant so that it may dispense a substance to the buccal mucosa of the wearer's mouth. The Kasdin Patent and the Sipos

Patent each disclose modifying an external buccal portion of a denture so that it may dispense a substance to the buccal mucosa of a wearer's mouth. The Sipos Patent further discloses an artificial tooth that may dispense a substance to the buccal mucosa of a wearer's mouth. The bar bell stud device disclosed by the Kaping Patent has no structure even remotely similar to the structure of Kasdin's or Sipos's dentures, or to Cox's crown, or to Sipos's artificial tooth. Therefore, a person of ordinary skill in the art would have lacked sufficient guidance to successfully modify Kaplan's bar bell structure to arrive at the presently claimed invention. Moreover, each one of the Kasdin Patent, the Cox Patent and the Sipos Patent discloses dispensing the substance to the buccal mucosa of the mouth, and away from the tongue. Therefore, a person of ordinary skill in the art would not have a reasonable expectation of success of modifying the device disclosed by the Kaping Patent, based on the disclosures of the Kasdin Patent, the Cox Patent, and/or the Sipos Patent, so that it would dispense a substance "on or below, or on and below, the wearer's tongue" in accordance with claims 21, 31, 36, 37, 38, 39, 44 and 45.

The Federal Circuit has held that the prior art must be enabling in order to support a determination of obviousness under 35 U.S.C. § 103. In re Kumar, 418 F.3d 1361, 1369 (Fed. Cir. 2005). The Federal Circuit has also held that in order to determine whether the prior art is enabling, which pertains to whether the prior art enables those skilled in the art to make and use the invention without "undue experimentation," one should consider various factors pertaining to whether undue experimentation would be required, such as (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. Impax Laboratories v. Aventis Pharmaceuticals Inc., 545 F.3d 1312, 1314-15 (Fed. Cir. 2008).

In this case, neither the Kaping Patent, the Kasdin Patent, the Cox Patent, nor the Sipos Patent, gives any guidance whatsoever regarding a device or method for dispensing a substance on or below, or on and below, the tongue of a wearer. Therefore, the second Impax factor strongly weighs

against enablement. Furthermore, neither the Kaping Patent, the Kasdin Patent, the Cox Patent, nor the Sipos Patent, provides any examples of a device or method for dispensing a substance on or below, or on and below, the tongue of a wearer. Therefore, the third Impax factor also strongly weighs against enablement. The nature of the invention is that it is a simple mechanical device in the art of body piercings, which is a relatively mature field. Therefore, the fourth and fifth Impax factors may weigh in favor of enablement. The skill of those in the art would be that of a jeweler, so the sixth Impax factor may be neutral or in favor of enablement. The predictability in the art is likely to be high, therefore, the seventh Impax factor may weigh in favor of enablement. However, because the art relied upon by the Examiner gives absolutely no guidance, or working examples, regarding the construction of a device for dispensing a substance on or below, or on and below, a wearer's tongue, the amount of experimentation required to arrive at the claimed invention may be high. Therefore, the first Impax factor should weigh against enablement. The scope of the claims is not relevant to whether the prior art enables the Examiner's hypothetical construct resulting from the combination of the Kaping Patent, the Kasdin Patent, the Cox Patent, and the Sipos Patent. Therefore, the eighth Impax factor should be construed as neutral.

In sum, the first, second and third Impax factors strongly weigh against enablement. Therefore, even assuming *arguendo* that the remaining factors weigh in favor of enablement (which is not a valid assumption), the Board should conclude that the above analysis of the Impax factors weighs against the enablement of the Examiner's method for dispensing a substance that utilizes a mouth and tongue stud provided with a means for dispensing as substance to dispense a substance "on or below, or on and below, the wearer's tongue" in accordance with claims 21, 31, 36, 37, 38, 39, 44 and 45 of the above-captioned application.

For all of the above reasons, the Board should conclude that the Examiner has failed to establish a prima facie case of obviousness against claims 21-27, 31, 36-39 and 42-49 of the above-captioned application.

**ix. The Examiner's Arguments with Respect to Ordinary Creativity, Common Knowledge and Common Sense are Untenable and Must be Withdrawn**

The Examiner argues that the claimed invention is, in some vague way, the result of common knowledge, common sense, and/or "ordinary creativity." (Office Action, dated August 19, 2010, at 12, lines 3-20). Applicant traverses the Examiner's conclusory arguments for the following reasons.

First, it is a well-settled proposition that an obviousness determination based on what the Examiner believes is "basic knowledge" and "common sense," and that otherwise lacks substantial evidentiary support, is not permitted. In re Zurko, 59 U.S.P.Q.2d 1693, 1697 (Fed.Cir. 2001). Therefore, Applicant respectfully traverses the Examiner's Section 103 rejection of all of the claims on the grounds that the apparent "Official Notice" lacks substantial evidentiary support. Therefore, to the extent the Examiner contends that a "mouth and tongue stud" provided with a means for dispensing a substance is common knowledge in the art, and/or common sense, Applicant objects. Such an "Official Notice" is factually false in view of the lengthy prosecution history of the above-captioned application. Therefore, the Examiner must now produce substantial evidentiary support (i.e., produce a prior art reference) to substantiate the Official Notice, or the obviousness rejections must all be withdrawn.

Second, the Examiner's conclusion of "ordinary creativity" is also without merit as the Examiner has failed to produce any evidence in support of the alleged "ordinary creativity" standard. On the contrary, the art of record, when considered as a whole, discloses methods for dispensing a substance to the buccal mucosa, and away from the wearer's tongue. This constitutes evidence of non-obviousness, as discussed above, and demonstrates that the present inventor has exercised more than "ordinary creativity" in developing the presently claimed invention.

The Examiner argues that "KSR forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness" (Office Action, dated August 19, 2010, at 12, lines 10-13). As discussed above, even if the combination of the Kaping Patent, the Kasdin

Patent, the Cox Patent, and the Sipos Patent is made, it still falls short of teaching, or suggesting, a method wherein “the substance is dispensed...on or below, or on and below, the wearer’s tongue” as recited by the independent claims. As also discussed above, the Examiner cannot make up this deficiency in the teachings of the prior art with an impermissible retrospective view of inherency (i.e., the Examiner cannot apply the inherency doctrine to the Examiner’s hypothetically constructed mouth and tongue stud). In re Newell, 13 U.S.P.Q.2d at 1250.

Lastly, while the Supreme Court’s decision in KSR International Co. v. Teleflex Inc. may have expanded the legitimate reasons for combining prior art beyond a specific teaching, suggestion, or motivation, expressly disclosed by a prior art reference, KSR International Co. v. Teleflex Inc., 127 S.Ct. 1727, 1739-42 (2007), it did not eliminate the need for establishing a “plausible rationale” to justify modifying the prior art, Power-One, Inc. v. Artesyn Technologies, Inc., 599 F.3d 1343, 1351-52 (Fed. Cir. 2010). As discussed above, the Kasdin Patent, the Cox Patent, and the Sipos Patent are all non-analogous art that teach away from dispensing a substance on or below the tongue. Therefore, the Examiner has not established any legitimate reason or plausible rationale for combining the Kasdin Patent, the Cox Patent and/or the Sipos Patent with the bar bell stud device disclosed by the Kaping Patent. This is additional evidence that the inventor exercised more than “ordinary creativity” in developing the claimed invention.

The Supreme Court’s decision in KSR also did not alter the requirement that obviousness rejections must be enabling. Impax Laboratories v. Aventis Pharmaceuticals Inc., 545 F.3d 1312, 1314-15 (Fed. Cir. 2008). For all of the reasons discussed above, the combination of the Kaping Patent, the Kasdin Patent, the Cox Patent, and the Sipos Patent is not enabling for the method recited by the claims of the above-captioned application. This is additional evidence that the inventor exercised more than “ordinary creativity” in developing the presently claimed invention.



For all of the above reasons, the Board should conclude that the Examiner has failed to establish a prima facie case of obviousness against claims 21-27, 31, 36-39 and 42-49 of the above-captioned application.

**ix. Applicant's Novel Invention Possesses a New Property that Merits**

**Patentability**

It is a well-settled proposition that a novel invention possessing a new property is not obvious. E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co., 7 U.S.P.Q.2d 1129, 1133-34 (Fed. Cir. 1988). In this case, the claimed invention is clearly novel over the art of record because no prima facie case of anticipation stands against any claim. The claimed invention possesses a clearly new property because Applicant's "mouth and tongue stud including a means for dispensing a substance formed in a portion of the stud" possesses the property or characteristic that it can mount in the tongue of a wearer to dispense a substance on or below, or on and below, the wearer's tongue. None of the prior art devices possess this remarkable new property or characteristic. This characteristic of Applicant's invention is utilized in the mounting and dispensing steps of the claimed method.

For all of the above reasons, the Board should conclude that Applicant's claimed invention, as recited by claims 21-27, 31, 36-39, and 42-49, is novel and possesses a new property that merits patentability over the art of record.

**B. Claims 21-27, 36, 44 and 46**

Claims 21-27, 36, 44 and 46 are patentable over the art of record for all of the reasons evinced above. In addition, the Examiner has failed to establish a prima facie case of obviousness against claims 21-27, 36, 44 and 46 because the combination of the Kaping Patent and the Kasdin Patent fails to teach, or even suggest, (i) "**providing a mouth and tongue stud including a means for dispensing a substance formed in a portion of the stud**" as recited by independent claims 21,

36, and 44, (ii)

“dispensing the substance into the wearer’s mouth, wherein the substance is dispensed on or below, or on and below, the wearer’s tongue solely by dissolving the substance over time in the wearer’s saliva so that the dissolved substance is free to flow from the means for dispensing to on or below, or on and below, the wearer’s tongue,”

as recited by claim 21, (iii)

“dispensing the substance into the wearer’s mouth, wherein the substance is dispensed on or below, or on and below, the wearer’s tongue solely by dissolving the substance over time in the wearer’s saliva,”

as recited by claim 36, and (vi)

“dispensing the substance into the wearer’s mouth, wherein the substance has a form selected from the group consisting of a solid form and a tablet form and is dispensed on or below, or on and below, the wearer’s tongue by dissolving the substance from the stud to flow on or below, or on and below, the wearer’s tongue over time in the wearer’s saliva,”

as recited by claim 44. For all of the reasons discussed above, the combined disclosures of the Kaping Patent and the Kasdin Patent do not teach, or suggest, a method wherein “the substance is dispensed on or below, or on and below, the wearer’s tongue” as recited by independent claims 21, 26 and 44, and the Examiner’s impermissible retrospective view of inherency cannot be used to make up this deficiency. For all of the reasons discussed above, the Examiner has failed to establish any legitimate reason to combine the disclosure of the Kasdin Patent, which is non-analogous art pertaining to dentures, with the disclosure of the Kaping Patent, which pertains to a bar bell stud device (i.e., a body piercing). For all of the reasons discussed above, the Kasdin Patent teaches away from a method for dispensing a substance on or under the tongue of a wearer, and the combination of the Kaping Patent and the Kasdin Patent is not enabling for such a method.

For all of the above reasons, the Board should conclude that the Examiner has failed to establish a prima facie case of obviousness against claims 21-27, 36, 44 and 46 of the above-captioned application.

**C. Claims 38 and 48**

Claims 38 and 48 are patentable over the art of record for all of the reasons evinced above. In addition, the Examiner has failed to establish a prima facie case of obviousness against claims 38 and 48 because the combination of the Kaping Patent and the Sipos Patent fails to teach, or even suggest, (i) “providing a mouth and tongue stud including a means for dispensing a substance formed in a portion of the stud” as recited by independent claim 38, and (ii)

“dispensing the substance into the wearer’s mouth, wherein the substance is dispensed into the wearer’s mouth on or below, or on and below, the wearer’s tongue by diffusing the substance from the stud into the wearer’s mouth over time in the wearer’s saliva,”

as recited by claim 38. For all of the reasons discussed above, the combined disclosures of the Kaping Patent and the Sipos Patent do not teach, or suggest, a method wherein “the substance is dispensed...on or below, or on and below, the wearer’s tongue” as recited by independent claim 38, and the Examiner’s impermissible retrospective view of inherency cannot be used to make up this deficiency. For all of the reasons discussed above, the Examiner has failed to establish any plausible rationale to combine the disclosure of the Sipos Patent, which is non-analogous art pertaining to dentures and an artificial tooth, with the disclosure of the Kaping Patent, which pertains to a bar bell stud device (i.e., a body piercing). For all of the reasons discussed above, the Sipos Patent teaches away from a method for dispensing a substance on or under the tongue of a wearer, and the combination of the Kaping Patent and the Sipos Patent is not enabling for such a method.

For all of the above reasons, the Board should conclude that the Examiner has failed to establish a prima facie case of obviousness against claims 38 and 48 of the above-captioned application.

**D. Claims 31, 37, 39, 42, 43, 45 and 47**

Claims 31, 37, 39, 42, 43, 45 and 47 are patentable over the art of record for all of the reasons evinced above. In addition, the Examiner has failed to establish a prima facie case of obviousness against claims 31, 37, 39, 42, 43, 45 and 47 because the combination of the Kaping Patent and the

Cox Patent fails to teach, or even suggest, (i) **“providing a mouth and tongue stud including a means for dispensing a substance formed in a portion of the stud”** as recited by independent claims 31, 37, 39 and 45, (ii)

**“dispensing the substance into the wearer’s mouth, wherein the substance is dispensed on or below, or on and below, the wearer’s tongue solely by dissolving the substance over time in the wearer’s saliva so that the dissolved substance is free to flow from the means for dispensing to on or below, or on and below, the wearer’s tongue,”**

as recited by claim 31, (iii)

**“dispensing the medication into the wearer’s mouth, wherein the medication is dispensed on or below, or on and below, the wearer’s tongue solely by dissolving the medication over time in the wearer’s saliva,”**

as recited by claim 37, (iv)

**“dispensing the substance into the wearer’s mouth, wherein the substance is dispensed into the wearer’s mouth on or below, or on and below, the wearer’s tongue by diffusing the substance from the stud into the wearer’s mouth over time in the wearer’s saliva,”**

as recited by claim 39, and (v)

**“dispensing the substance into the wearer’s mouth, wherein the substance has a form selected from the group consisting of a solid form and a tablet form and is dispensed on or below, or on and below, the wearer’s tongue by dissolving the substance from the stud to flow on or below, or on and below, the wearer’s tongue over time in the wearer’s saliva,”**

as recited by claim 45. For all of the reasons discussed above, the combined disclosures of the Kaping Patent and the Cox Patent do not teach, or suggest, a method wherein “the substance is dispensed...on or below, or on and below, the wearer’s tongue” as recited by independent claims 31, 37, 39 and 45, and the Examiner’s impermissible retrospective view of inherency cannot be used to make up this deficiency. For all of the reasons discussed above, the Examiner has failed to establish any plausible rationale to combine the disclosure of the Cox Patent, which is non-analogous art pertaining to dental crowns and implants, with the disclosure of the Kaping Patent, which pertains to a bar bell stud device (i.e., a body piercing). For all of the reasons discussed above, the Cox Patent teaches away from a method for dispensing a substance on or under the tongue of a wearer, and the

combination of the Kaping Patent and the Cox Patent is not enabling for such a method.

For all of the above reasons, the Board should conclude that the Examiner has failed to establish a prima facie case of obviousness against claims 31, 37, 39, 42, 43, 45 and 47 of the above-captioned application.

**E. Claim 49**

Claim 49, which depends upon claim 39, is patentable over the art of record for all of the reasons evinced above. In addition, the Examiner has failed to establish a prima facie case of obviousness against claim 49 because the combination of the Kaping Patent with the Cox Patent and the Kasdin Patent fails to teach, or even suggest, (i) “**providing a mouth and tongue stud including a means for dispensing a substance formed in a portion of the stud**” as recited by independent claim 39, and (ii)

**“dispensing the substance into the wearer’s mouth, wherein the substance is dispensed into the wearer’s mouth on or below, or on and below, the wearer’s tongue by diffusing the substance from the stud into the wearer’s mouth over time in the wearer’s saliva,”**

as recited by claim 39. For all of the reasons discussed above, the combined disclosures of the Kaping Patent, the Cox Patent and the Kasdin Patent do not teach, or suggest, a method wherein “the substance is dispensed into the wearer’s mouth on or below, or on and below, the wearer’s tongue” as recited by independent claim 39, and the Examiner’s impermissible retrospective view of inherency cannot be used to make up this deficiency. For all of the reasons discussed above, the Examiner has failed to establish any plausible rationale to combine the disclosure of the Cox Patent, which is non-analogous art pertaining to dental crowns and implants, and the Kasdin Patent, which is non-analogous art pertaining to dentures, with the disclosure of the Kaping Patent, which pertains to a bar bell stud device (i.e., a body piercing). For all of the reasons discussed above, the Cox Patent and the Kasdin Patent teach away from a method for dispensing a substance on or under the tongue of a wearer, and the combination of the Kaping Patent with the Cox Patent and the Kasdin Patent is not enabling for such a method.

For all of the above reasons, the Board should conclude that the Examiner has failed to establish a prima facie case of obviousness against claim 49 of the above-captioned application.

2. **CONCLUSION**

For all of the above reasons, the Board should conclude that the Examiner has failed to establish a prima facie case of obviousness against claims 21-27, 31, 36-39 and 42-49 under 35 U.S.C. § 103 because the combination of the Kaping Patent, the Kasdin Patent, the Cox Patent, and the Sipos Patent, (i) fails to teach each and every limitation of the claims, and (ii) the Examiner has failed to establish any plausible rationale whatsoever to justify the alleged combinations, and (iii) the Examiner has failed to establish that a person of ordinary skill in the art would have had a reasonable expectation of success of obtaining the claimed invention even if the combinations of the Kaping Patent, the Kasdin Patent, the Cox Patent, and the Sipos Patent, were made. Therefore, it is respectfully submitted that the pending claims are allowable, and reversal of the rejections is respectfully requested.

Respectfully submitted,

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**CLAIMS APPENDIX (A):**

Claims 1-20 have been canceled.

21. A method for dispensing a substance into a mouth, wherein the substance is selected from the group consisting of a breath freshener and a flavoring agent, the method comprising the steps of:

providing a mouth and tongue stud including a means for dispensing a substance formed in a portion of the stud, wherein the means for dispensing a substance contains the substance and wherein the stud further comprises a bar having ends, a first end member attached to one end of the bar and a second end member attached to an other end of the bar, and the first end member removably attaches to the one end of the bar;

mounting the bar of the stud in a fistula formed in a wearer's tongue; and

dispensing the substance into the wearer's mouth, wherein the substance is dispensed on or below, or on and below, the wearer's tongue solely by dissolving the substance over time in the wearer's saliva so that the dissolved substance is free to flow from the means for dispensing to on or below, or on and below, the wearer's tongue.

22. A method as recited in claim 21, wherein the substance comprises a breath freshener.

23. A method as recited in claim 21, wherein the substance comprises a flavoring agent.

24. A method as recited in claim 23, wherein the substance includes a breath freshener mixed with the flavoring agent.

25. A method as recited in claim 22, wherein a medication is mixed with the breath freshener.

26. A method as recited in claim 23, wherein a medication is mixed with the flavoring agent.

27. A method as recited in claim 24, wherein a medication is mixed with the breath freshener and the flavoring agent.

28. (Cancelled)

29. (Cancelled)

30. (Cancelled)

31. A method for dispensing a substance into a mouth, wherein the substance is a medication, the method comprising the steps of:

providing a mouth and tongue stud including a means for dispensing a substance formed in a portion of the stud, wherein the means for dispensing a substance contains the medication and wherein the stud comprises a bar having ends, a first end member attached to one end of the bar and a second end member attached to an other end of the bar, and the first end member removably attaches to the one end of the bar;

mounting the bar of the stud in a fistula formed in a wearer's tongue; and

dispensing the medication into the wearer's mouth, wherein the substance is dispensed on or below, or on and below, the wearer's tongue solely by dissolving the substance over time in the wearer's saliva so that the dissolved substance is free to flow from the means for dispensing to on or below, or on and below, the wearer's tongue.



32. (Canceled)

33. (Canceled)

34. (Canceled)

35. (Canceled)

36. A method for dispensing a substance into a mouth, wherein the substance is selected from the group consisting of a breath freshener and a flavoring agent, the method comprising the steps of:

providing a mouth and tongue stud including a means for dispensing a substance formed in a portion of the stud, wherein the means for dispensing a substance contains the substance and wherein the stud comprises a bar having ends, a first end member attached to one end of the bar and a second end member attached to an other end of the bar, wherein the bar is a straight solid bar that is without an internal cavity and that is made of metal and the first end member removably attaches to the one end of the bar, and wherein the means for dispensing a substance is formed in one or both of the first end member and the second end member;

mounting the bar of the stud in a fistula formed in a part of a wearer's mouth; and

dispensing the substance into the wearer's mouth, wherein the substance is dispensed on or below, or on and below, the wearer's tongue solely by dissolving the substance over time in the wearer's saliva.

37. A method for dispensing a substance into a mouth, wherein the substance is a medication, the method comprising the steps of:

providing a mouth and tongue stud including a means for dispensing a substance formed in a portion of the stud, wherein the means for dispensing a substance contains the medication and wherein the stud comprises a bar having ends, a first end member attached to one end of the bar and a

second end member attached to an other end of the bar, wherein the bar is a straight solid bar that is without an internal cavity and that is made of metal and the first end member removably attaches to the one end of the bar, and wherein the means for dispensing a substance is formed in one or both of the first end member and the second end member;

mounting the bar of the stud in a fistula formed in a part of a wearer's mouth; and

dispensing the medication into the wearer's mouth, wherein the medication is dispensed on or below, or on and below, the wearer's tongue solely by dissolving the medication over time in the wearer's saliva.

38. A method for dispensing a substance into a mouth, wherein the substance is selected from the group consisting of a breath freshener and a flavoring agent, the method comprising the steps of:

providing a mouth and tongue stud including a means for dispensing a substance formed in a portion of the stud, wherein the means for dispensing a substance contains the substance and wherein the stud further comprises a bar having ends, a first end member attached to one end of the bar and a second end member attached to an other end of the bar, and the first end member removably attaches to the one end of the bar, and wherein an insert is disposed in the means for dispensing a substance;

mounting the bar of the stud in a fistula formed in a wearer's tongue so that the first end member and the second end member hold the stud in the fistula; and

dispensing the substance into the wearer's mouth, wherein the substance is dispensed into the wearer's mouth on or below, or on and below, the wearer's tongue by diffusing the substance from the stud into the wearer's mouth over time in the wearer's saliva.

39. A method for dispensing a substance into a mouth, wherein the substance is a medication, the method comprising the steps of:

providing a mouth and tongue stud including a means for dispensing a substance formed in a

portion of the stud, wherein the means for dispensing a substance contains the substance and wherein the stud further comprises a bar having ends, a first end member attached to one end of the bar and a second end member attached to an other end of the bar, and the first end member removably attaches to the one end of the bar, and wherein an insert is disposed in the means for dispensing a substance;

mounting the bar of the stud in a fistula formed in a wearer's tongue so that the first end member and the second end member hold the stud in the fistula; and

dispensing the substance into the wearer's mouth, wherein the substance is dispensed into the wearer's mouth on or below, or on and below, the wearer's tongue by diffusing the substance from the stud into the wearer's mouth over time in the wearer's saliva.

40. (Cancelled)

41. (Cancelled)

42. A method as recited in claim 44, wherein the substance has a solid form and the solid form is a solid crystallized form.

43. A method as recited in claim 45, wherein the substance has a solid form and the solid form is a solid crystallized form.

44. A method for dispensing a substance into a mouth, wherein the substance is selected from the group consisting of a breath freshener and a flavoring agent, the method comprising the steps of:

providing a mouth and tongue stud including a means for dispensing a substance formed in a portion of the stud, wherein the means for dispensing a substance contains the substance and wherein the stud further comprises a bar having ends, a first end member attached to one end of the bar and a second end member attached to an other end of the bar, and the first end member removably attaches

to the one end of the bar;

mounting the bar of the stud in a fistula formed in a wearer's tongue so that the first end member and the second end member hold the stud in the fistula; and

dispensing the substance into the wearer's mouth, wherein the substance has a form selected from the group consisting of a solid form and a tablet form and is dispensed on or below, or on and below, the wearer's tongue by dissolving the substance from the stud to flow on or below, or on and below, the wearer's tongue over time in the wearer's saliva.

45. A method for dispensing a substance into a mouth, wherein the substance is a medication, the method comprising the steps of:

providing a mouth and tongue stud including a means for dispensing a substance formed in a portion of the stud, wherein the means for dispensing a substance contains the substance and wherein the stud further comprises a bar having ends, a first end member attached to one end of the bar and a second end member attached to an other end of the bar, and the first end member removably attaches to the one end of the bar;

mounting the bar of the stud in a fistula formed in a wearer's tongue so that the first end member and the second end member hold the stud in the fistula; and

dispensing the substance into the wearer's mouth, wherein the substance has a form selected from the group consisting of a solid form and a tablet form and is dispensed on or below, or on and below, the wearer's tongue by dissolving the substance from the stud to flow on or below, or on and below, the wearer's tongue over time in the wearer's saliva.

46. A method as recited in claim 22, wherein the bar is a solid bar that is without an internal cavity, and the means for dispensing a substance is formed in the second end member.

47. A method as recited in claim 31, wherein the bar is a solid bar that is without an

internal cavity, and the means for dispensing a substance is formed in the second end member.

48. A method as recited in claim 38, wherein the substance comprises a liquid.

49. A method as recited in claim 39, wherein the substance comprises a liquid.

**EVIDENCE APPENDIX (B):**

1. GRAY'S ANATOMY 1413-1417 and 1432 (Carmine D. Clemente ed., Lea & Fabringer 1985), which was filed as "Exhibit AD" on July 12, 2010. A copy of Exhibit AD is filed herewith.

**RELATED PROCEEDINGS APPENDIX (C):**

There are no Related Proceedings for this appeal as indicated on the attached Related Proceedings Appendix.